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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/035,091

12/21/2001

Holly Hogrefe

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

11/13/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/035,091

Applicant(s)

HOGREFE ET AL.

Examiner

Richard G. Hutson

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1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,10-12,14,20,22-24,26 and 30-51 is/are pending in the application.
- 4a) Of the above claim(s) 23-26 and 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 14 and 48-51 is/are rejected.
- 7) ☒ Claim(s) 1,10-12,20,22 and 36-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's cancellation of claim 2, 13 and 25 and the amendment of claims 1, 10, 12, 22, 23, 26, 36, 37 and 38-50, in the paper of 8/31/2007, is acknowledged. Applicants' arguments filed on 8/31/2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Claims 1, 3, 10-12, 14, 20, 22-24, 26, and 30-51 are still at issue and are present for examination

Claims 23-26 and 30-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claims 1, 10-12, 20, 22, 36-51 are objected to because of the following informalities:

Claims 1 (claims 10, 11 dependent from) 12, (claim 20 dependent from), 22, 36 (claims 37-39 dependent from), 40 (claims 41-43 dependent from), 41, 44 (claims 46, 47 dependent from), 45, 48, 49 and 50 (claim 51 dependent from) recite "...G387, and G388, and...". It is suggested that each of the commas preceding "and" be deleted. Applicants previous comments regarding this earlier made objection are noted, however, not found persuasive and thus maintained.

Claim 10, 22, 41, 45 are objected to because the newly added language, "is mutated at one or more amino acid positions to create one or more amino acid

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substitutions, and the resulting ..." adds nothing to the claim other than confusion. The following explanation is relative to claim 10, but claims 22 and 41 are similarly objected to. Since this claim is dependent from claim 1 and therefore requires each of the limitations of claim 1 and it appears that the intent is to further define the mutations of claim 1 or 12, respectively, it is suggested that the limitations of claim 10 be directed to the mutations rather than the polymerase. An example (for claim 10) might read such as:

The enzyme mixture of claim 1, wherein said mutation(s) consist(s) of one or more amino acid substitutions selected from the group consisting of: Y410F, T542P, D543G, K593T, Y595S, Y385Q, Y385S, Y385N, Y385L, Y385H, G387S, G387P, and G388P.

Claim 45 recites "substituteions". This should be "substitutions".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 14 are indefinite in that it depends from cancelled claims 2 and 13. For the purpose of advancing prosecution, claims 3 and 14 are interpreted as if they depend from claims 1 and 12.

Appropriate correction is suggested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 1, 10, 11, 12, 20 and 22. In response to the rejection, applicants have amended claims 1, 10, 12, 22, 23, 26, 36, 37 and 38-50 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection on the basis that applicants have amended the claims to recite a DNA polymerase or reverse transcriptase and state that they were in possession of the invention recited in the amended claims and accordingly request that the rejection be reconsidered and withdrawn

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Applicant's amendment and complete argument is acknowledged and has been carefully considered, however, is found non-persuasive for claims 48-51 for the reasons previously made of record and repeated herein. The basis for this rejection is applicant's recitation in these claims to "Pfu DNA polymerase, except that it is mutated in **at least** one amino acid position...". This recited limitation of the second enzyme of the claimed kits removes the necessary structural limitations of the required to adequately describe the second enzyme which started out prior to any mutation as Pfu DNA polymerase. Applicant's attention is particularly directed to the wording "at least", as it compares to the wording of applicants claim 1. Such language of the instant claim is interpreted as allowing additional mutations outside the referenced positions, such that applicants have not adequately described this genus.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 48-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an enzyme mixture comprising a first and second enzyme, wherein said first enzyme is a DNA polymerase or reverse transcriptase and said second enzyme is a Pfu DNA polymerase which comprises the amino acid sequence of SEQ ID NO: 19 with a mutation selected from the group consisting of Y410, T542, D543, K593, Y595, Y385, G387 and G388, does not reasonably provide enablement for an enzyme mixture comprising a first and second enzyme, wherein said

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first enzyme is a DNA polymerase or reverse transcriptase and said second enzyme is a mutant Pfu DNA polymerase except that it is mutated in at least one amino acid position selected from the group consisting of: Y410, T542, D543, K593, Y595, Y385, G387 and G388. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1, 10, 11, 12, 20 and 22. In response to the rejection, applicants have amended claims 1, 10, 12, 22, 23, 26, 36, 37 and 38-50 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection on the basis that applicants have amended the claims to recite a DNA polymerase or reverse transcriptase and state that they were in possession of the invention recited in the amended claims and accordingly request that the rejection be reconsidered and withdrawn

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however, is found non-persuasive for claims 48-51 for the reasons previously made of record and repeated herein. The basis for this rejection is applicant's recitation in these claims to "Pfu DNA polymerase, except that it is mutated in **at least** one amino acid position...". This recited limitation of the second enzyme of the claimed kits removes the necessary structural limitations of the required to adequately describe the second enzyme which started out prior to any mutation as Pfu DNA polymerase. Applicant's attention is particularly directed to the wording "at least",

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as it compares to the wording of applicants claim 1. Such language of the instant claim is interpreted as allowing additional mutations outside the referenced positions, such that applicants have not enabled this genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any enzyme mixture comprising any Pfu DNA polymerase with at least the specified mutations. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of enzymes having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 10-12, 14, 20, 22 and 36-51 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 64-70, 75-87 of copending Application No. 10/079,241. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed enzyme mixtures of the instant application, comprising a first enzyme and a second enzyme wherein said first enzyme comprises a DNA polymerization activity and said second enzyme is a mutant Pfu DNA polymerase having a mutation at an amino acid position selected from the group consisting of D405, Y410, T542, K593, Y595, Y385, Y387, and G388 and those further limited claims dependent thereon are anticipated by and thus obvious over the corresponding claims of copending Application No. 10/079,241, drawn to a enzyme mixture comprising a first enzyme and a second enzyme wherein said first enzyme is an Archaeal DNA polymerase and said second enzyme is a mutant Archaeal DNA polymerase having a mutation at an amino acid position selected from the group consisting of D405, Y410, T542, K593, Y595, Y385, Y387, and G388 and those further limited claims dependent thereon.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant acknowledgment of this provisional rejection is acknowledged, as well as applicant's statement of their intent of filing a terminal disclaimer as a means of overcoming the rejection at the time at which the claims are found otherwise allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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11/6/2007